IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW MEXICO

AMBERCARE HOSPICE, INC.,

Plaintiff,

v.

Case No. 24-cv-285

XAVIER BECERRA, in his official capacity as Secretary of the United States Department of Health & Human Services,

Defendant.

COMPLAINT FOR JUDICIAL REVIEW OF ADMINISTRATIVE DECISION

Plaintiff AMBERCARE HOSPICE, INC. (the "Hospice"), by and through its undersigned counsel, files this Complaint against Defendant XAVIER BECERRA, in his official capacity as the Secretary of the United States Department of Health and Human Services (the "Secretary"), seeking judicial review of the decision rendered by the Administrative Law Judge ("ALJ") of the Office of Medicare Hearings and Appeals ("OMHA") in OMHA case number 3-11243442216 and in relation to Medicare Appeals Council ("Council") docket number M-23-5481.

PARTIES, JURISDICTION, AND VENUE

1. The Hospice is a New Mexico corporation with its principal place of business located at 2129 Osuna Road Northeast, Albuquerque, New Mexico 87113.

2. At all times relevant hereto, the Hospice was a Medicare-certified company offering hospice services in New Mexico.

3. Defendant, Xavier Becerra, is the Secretary of the United States Department of Health and Human Services and the proper defendant in this action pursuant to 42 C.F.R. § 405.1136(d)(1).

4. This action arises under the United States Constitution, Title XVIII of the Social Security Act, 42 U.S.C. § 1395 *et seq*. ("Medicare Act"), and the Administrative Procedure Act, 5 U.S.C. § 551 *et seq.* (the "APA").

5. Prior to filing this Complaint, the Hospice filed appeals and received determinations as to all issues presented below.

6. The Council did not issue a final decision or dismissal order or remand the case to the ALJ within 90 calendar days of receipt of the Hospice's Request for Review. *See* 42 C.F.R. § 405.1100(c). Accordingly, on January 11, 2024, the Hospice properly requested that the appeal be escalated to federal district court as permitted by 42 C.F.R. § 405.1132(a). On January 23, 2024, the Council issued an order granting the Hospice's request for escalation. The ALJ's decision is the final administrative decision and is appealable to this Court under 42 C.F.R. §1395ff(b), 42 C.F.R. §405.1132, and 42 C.F.R. §405.1136.

7. Therefore, because the Hospice has exhausted all administrative appeals and, thus, has no administrative remedy available to it, this Court is the proper forum to hear this Complaint.

8. As mandated by 42 C.F.R. §§ 405.1132(b), 1136(c)(1), this action has been commenced within 60 days of receipt of the Council's notice dated January 23, 2024 that it is not able to timely issue a final decision, dismissal order, or remand order.

9. Jurisdiction is proper pursuant to 28 U.S.C. § 1331, which vests federal district courts with "original jurisdiction of all civil actions arising under the Constitution, laws, or treaties of the United States," and 42 U.S.C. § 1395ff(d), which authorizes judicial review of the ALJ's decision.

10. Venue is proper pursuant to 42 U.S.C. § 1395ff(b) and 42 C.F.R. §405.1136(b)(1), as the Hospice's principal place of business is located in this judicial district.

11. The amount in controversy exceeds the threshold amount of $1,840.00 for judicial review set forth in 88 Federal Register 67297 (effective Jan. 1, 2024).

LEGAL FRAMEWORK: PROCEDURAL DUE PROCESS

12. The Fifth and Fourteenth Amendments of the U.S. Constitution guarantee rights to procedural due process. *See* U.S. Const. amend. V; U.S. Const. amend. XIV, § 1.

13. Procedural due process constrains "governmental decisions which deprive individuals of 'liberty' or 'property' interests within the meaning of the Due Process Clause of the Fifth or Fourteenth Amendment." *Mathews v. Eldridge*, 424 U.S. 319, 332 (1976).

14. To demonstrate violation of procedural due process rights, a plaintiff must show that the individual (1) had a protected property interest and (2) was deprived of an appropriate level of process. *See Camuglia v. City of Albuquerque*, 448 F.3d 1214, 1219 (10th Cir. 2006).

15. To have a constitutionally protected property interest in a benefit, a person clearly must have "a legitimate claim of entitlement to it." *Bd. of Regents of State Colleges v. Roth*, 408 U.S. 564 (1972).

16. To determine whether the procedures at issue were constitutionally adequate, courts consider: (1) the private interest affected, (2) the government's interest, and (3) the risk of erroneous deprivation of the private interest under the procedures used. *Mathews*, 424 U.S. at 335.

17. Hospices are statutorily entitled to be paid for services provided to Medicare beneficiaries that meet Medicare program requirements. *See* 42 U.S.C. § 1395f.

18. The Healthcare Care Financing Administration (the predecessor to CMS) has indicated that when challenging the use of statistical sampling to project overpayments, providers can vindicate their rights to procedural due process only if they have a "full opportunity to demonstrate that the overpayment determination is wrong." Health Care Fin. Admin., Use of

Statistical Sampling to Project Overpayments to Medicare Providers and Suppliers, Ruling No. 86-1 (Feb. 20, 1986).

LEGAL FRAMEWORK: THE MEDICARE HOSPICE BENEFIT

19. The Medicare Hospice Benefit is a benefit under Medicare Part A, a 100% federally subsidized health insurance program. It is administered by the Centers for Medicare and Medicaid Services ("CMS") on behalf of the Department of Health and Human Services ("HHS"). The Medicare Hospice Benefit pays a predetermined fee, based on the level of care provided by the hospice provider, for each day an eligible individual receives hospice care.

20. Through the Medicare Hospice Benefit, Medicare covers reasonable and necessary hospice services provided to eligible individuals. Services available under the Medicare Hospice Benefit are "comprehensive" and include (a) nursing care and services provided by or under the supervision of a registered nurse, (b) medical social services provided by a qualified social worker under the direction of a physician, (c) physician services, (d) counseling services, including bereavement, dietary, and spiritual counseling, (e) short-term inpatient care, (f) medical supplies, including drugs and biologicals, (g) home health aide / homemaker services, and (h) physical, respiratory, occupational, and speech therapy services. 42 C.F.R. § 418.202; *see also* 42 C.F.R. § 418.3; 42 U.S.C. § 1395x(dd).

21. To receive the Medicare Hospice Benefit, an eligible individual must file an election statement acknowledging that he or she "has been given a full understanding of the palliative rather than curative nature of hospice care, as it relates to the individual's terminal illness and related conditions." 42 C.F.R. § 418.24. Palliative care is "patient and family-centered care that optimizes quality of life by anticipating, preventing, and treating suffering[;]…addressing physical, intellectual, emotional, social, and spiritual needs[;] and…facilitat[ing] patient

autonomy, access to information, and choice." 42 C.F.R. § 418.3. The election statement must also acknowledge that "certain Medicare services" are waived by the election, namely "Medicare services that are related to the treatment of the terminal condition for which hospice care was elected or a related condition," except for services provided by the designated hospice or the individual's attending physician. 42 C.F.R. § 418.24; *see also* 42 U.S.C. § 1395y(a)(1)(c) ("[N]o payment may be made…for any expenses incurred for items or services…in the case of hospice care, which are not reasonable and necessary for the palliation or management of terminal illness."). Individuals are free to revoke the election of the Medicare Hospice Benefit at any time and for any reason. 42 C.F.R. § 418.28.

22. The government conditions reimbursement to providers of hospice services on a certification of hospice eligibility. 42 U.S.C. § 1395f. The Medicare Hospice Benefit is organized around benefit periods, *i.e.*, two 90-day benefit periods followed by an unlimited number of 60-day benefit periods. 42 U.S.C. § 1395d(a)(4). The hospice provider must obtain a written certification that the individual is terminally ill (a "CTI") "at the beginning of [each benefit] period" and "before it submits a claim for payment." 42 U.S.C. § 1395f(a)(7)(A); 42 C.F.R. § 418.22. For the initial 90-day benefit period, a hospice provider must obtain a CTI from (1) the hospice's medical director or a physician in the hospice interdisciplinary group (a "Hospice Physician"), and (2) the individual's designated attending physician (the "Designated Attending") (if any). For all subsequent benefit periods, a CTI need only be obtained from a Hospice Physician. 42 U.S.C. § 1395f(a)(7)(A)(ii).

23. Given the nuances and complexities involved in prognostication, as described below, Congress and CMS have entrusted physicians with the responsibility to determine whether a patient meets the definition of "terminally ill." 42 U.S.C. § 1395f(a)(7); 70 Fed. Reg. 70532,

70539 (Nov. 22, 2005) ("It is the physician's responsibility to assess the patient's medical condition and determine if the patient can be certified as terminally ill."). An individual is "terminally ill" when the Designated Attending (if applicable) and a Hospice Physician exercise their clinical judgment to conclude that "the individual has a medical prognosis that his or her life expectancy is 6 months or less if the illness runs its normal course." 42 U.S.C. § 1395x(dd)(3)(A); 42 C.F.R. § 418.3. A "life expectancy" of 6 months or less means that, in the clinical judgement of the Designated Attending (if applicable) and a Hospice Physician, the individual's clinical status at the time of certification is more likely than not (*i.e.*, a probability of > 50%) to result in death within six months based on the normal course of the individual's illness. 42 C.F.R. § 418.3.

24. Several changes have been made to the Medicare Hospice Benefit over the years to ensure that Designated Attendings and Hospice Physicians who complete CTIs ("Certifying Physicians") are closely involved in evaluating individuals to predict prognosis and determine eligibility. *See, e.g.*, 75 Fed. Reg. 43236 (July 23, 2010). For example, CTIs must now include a narrative description of the individual ("CTI Narrative") and an attestation "confirm[ing] that [the Certifying Physician] composed the narrative based on his/her review of the patient's medical record or, if applicable, his/her examination of the patient." 42 C.F.R. § 418.22(b)(3)(iii). Additionally, CTIs for all 60-day benefit periods must be preceded by a "face-to-face encounter" ("F2F") in which a Hospice Physician or hospice nurse practitioner visits an individual to gather clinical findings to determine their continued eligibility for hospice care. Certifying Physicians must explain, in the CTI Narrative, why the F2F clinical findings support a life expectancy of 6 months or less. 42 C.F.R. § 418.22(a)(4) and (b)(3)(v).

25. When Certifying Physicians evaluate an individual's eligibility for hospice, they look at *prognosis*, not diagnosis. "[E]ligibility for hospice services under the [Medicare Hospice

Benefit] has always been based on the prognosis of the individual, not [the] diagnosis." 78 Fed. Reg. 48234, 48245 (Aug. 7, 2013). Prognosis takes into account diagnoses and all other things related to an individual's life expectancy. 78 Fed. Reg. 48234, 48245–46; *see also* 79 Fed. Reg. 50452, 50469 (Aug. 22, 2014) ("[T]he individual's whole condition plays a role in that prognosis."). Thus, Certifying Physicians "must consider the primary terminal condition, related diagnoses, current subjective and objective medical findings, current medication and treatment orders, and information about unrelated conditions when considering the initial certification of the terminal illness." 73 Fed. Reg. 32088, 32138 (June 5, 2008); *see also* 42 C.F.R. § 418.25(b) ("In reaching a decision to certify that the patient is terminally ill, the hospice medical director must consider at least the following information: (1) Diagnosis of the terminal condition of the patient; (2) Other health conditions, whether related or unrelated to the terminal condition; (3) Current clinically relevant information supporting all diagnoses.").

26. While a prognosis of a life expectancy of six months or less is a necessary condition for reimbursement, Congress has acknowledged that "[p]redicting life expectancy is not an exact science." *See* 142 Cong. Rec. S9582 (daily ed. Aug. 2, 1996) (statement of Sen. Breaux); *see also* 75 Fed. Reg. 70372, 70488 (Nov. 17, 2010). The phrase "if the illness runs its normal course" in the definition of "terminal illness" is an important recognition by CMS that a physician's determination of patient prognosis cannot, nor need not, be a certainty. *See* 55 Fed. Reg. 50831, 50832 (Dec. 11, 1990) (citing Government Accounting Office, *Program Provisions and Payments Discourage Hospice Participation* (Sept. 29, 1989)). CMS has also recognized that there will be variability in lengths of stay because "individuals vary in their responses to illness and care," and it is not "feasible or prudent to specify or predetermine what lengths of stay should or must be achieved to measure or evaluate the effectiveness of care provided." *See* 72 Fed. Reg. 50214,

50222 (Aug. 31, 2007). Therefore, "[t]he fact that a beneficiary lives longer than expected in itself is not cause to terminate benefits." Medicare Benefit Policy Manual, CMS Pub. No. 100-02, Ch. 9, § 10.

27. The current Medicare framework does not preclude reimbursement for periods of hospice care that extend beyond six months. There used to be a 210-day statutory limit on hospice care, but Congress removed that limitation in 1989 in recognition of the uncertainty of prognosis. *See* 42 U.S.C. § 1395d(d)(1) (establishing that hospice providers may collect reimbursement for an unlimited number of benefit periods); *see also* Medicare Catastrophic Coverage Repeal Act of 1989; 70 Fed. Reg. 70532, 70533 (Nov. 22, 2005). In a Program Memorandum to Intermediaries/Carriers, CMS has stated:

> Recognizing that prognoses can be uncertain and may change, Medicare's benefit is not limited in terms of time. Hospice care is available as long as the patient's prognosis meets the law's six-month test. This test is a general one. As the governing statute says: "The certification of terminal illness of an individual who elects hospice shall be based on the physician's or medical director's clinical judgment regarding the normal course of the individual's illness." CMS recognizes that making medical prognostication of life expectancy is not always an exact science. ***Thus, physicians need not be concerned. There is no risk to a physician about certifying an individual for hospice care that he or she believes to be terminally ill***.

Program Memorandum Intermediaries/Carriers, Subject: Provider Education Article, CMS-Pub. 60AB (Mar. 28, 2003) (quoting 42 U.S.C. § 1395f(a)(7)) (emphasis added).

28. CMS has not created clinical benchmarks that must be satisfied to certify a patient as terminally ill. In 2008, CMS announced a rule specifying the information a Certifying Physician "must consider" in making an initial certification. *See* 42 C.F.R. § 418.102(b). CMS initially proposed labeling the considerations "criteria," but removed that word, explaining:

> In the proposed rule, we called [the considerations] "criteria," and we believe that this term may have been the source of commenter concern. Our intent was to ensure that medical directors carefully examine all relevant information that is gathered about the patient before making [an eligibility] determination…. ***We have removed***

> ***the term "criteria" in order to remove any implication that there are specific CMS clinical benchmarks in this rule that must be met in order to certify terminal illness.***

73 Fed. Reg. 32088, 32138 (June 5, 2008) (emphasis added).

29. CMS has recognized that seemingly straightforward clinical courses in a patient's condition, such as a decline or stabilization, are much more nuanced in relation to determining terminality, such that neither a lack of decline nor stabilization necessarily negate a terminal prognosis:

> [B]eneficiaries in the terminal stage of their illness that originally qualify for the [Medicare Hospice Benefit] but stabilize or improve while receiving hospice care, yet have a reasonable expectation of continued decline for a life expectancy of less than 6 months, remain eligible for hospice care. The [Certifying Physician] must assess and evaluate the full clinical picture of the Medicare hospice beneficiary to make the determination whether the beneficiary still has a medical prognosis of 6 months or less, regardless of whether the beneficiary has stabilized or improved.

See 79 Fed. Reg. 50452, 50471 (Aug. 22, 2014) (emphasis added); *see also* 75 Fed. Reg. 70372, 70448 (Nov. 17, 2010) ("A patient's condition may temporarily improve with hospice care."); 74 Fed. Reg. 39384, 39399 (Aug. 6, 2009) ("We also acknowledge that at recertification, not all patients may show measurable decline."). Based on CMS guidance, a federal district court has excluded proposed expert testimony alleging that an individual must show decline to remain eligible for hospice. *See Vista Hospice Care*, No. 3:07-CV-00604-M, 2016 WL 3449833, at *15 (N.D. Tex. June 20, 2016) (citing 79 Fed. Reg. 50452, 50471 (Aug. 22, 2014)). Moreover, CMS has acknowledged that a perceived improvement or stabilization (*i.e.*, an apparent lack of decline) in symptoms may not mean that an individual's *prognosis* (on which hospice eligibility is based) has changed, and it can be difficult to distinguish a sustainable stabilization from the *impression* of stabilization that could not be maintained if the patient were to be discharged from hospice. *See* 70 Fed. Reg. 70532, 70540 (Nov. 22, 2005); *see also* 79 Fed. Reg. 50452, 50471 (Aug. 22, 2014).

30. CMS contracts with Medicare Administrative Contractors ("MACs"), which are private companies that process and pay Medicare claims on behalf of CMS. MACs issue Local Coverage Determinations ("LCDs"), which are "administrative and educational tools" that give "guidance to the public and medical community" within a specific geographical area in order "to assist providers in submitting correct claims." *See* CMS Transmittal 608, Medicare Program Integrity Manual, Ch. 13.1.3 (August 14, 2015), available at https://www.cms.gov/Regulations-and- Guidance/Guidance/Transmittals/downloads/R608PI.pdf.

31. Hospice LCDs set forth clinical *guidelines* to be considered when assessing an individual's terminality; they do not impose a set of mandatory clinical data-points that must be documented in the medical record to demonstrate hospice eligibility. LCDs do not and *cannot* establish or change the substantive legal standard for hospice eligibility because LCDs have not gone through the notice-and-comment process outlined at 42 U.S.C. § 1395hh. *See Agendia, Inc. v. Becerra*, 4 F.4th 896, 900 (9th Cir. 2021). Accordingly, eligibility for hospice cannot be limited by LCDs if an individual otherwise satisfies the only valid and substantive legal standard applicable: a determination by a physician of a prognosis of six months or less if the individual's illness runs its normal course. 42 U.S.C. § 1395x(dd)(3)(A); 42 C.F.R. § 418.3. In other words, LCDs represent only one of an indefinite number of ways Certifying Physicians may support their conclusion that an individual has a terminal prognosis under the statutory and regulatory standard. *Vista Hospice Care*, 2016 WL 3449833, at *4 ("Meeting…[LCD guidelines] is *one path* to eligibility under the [Medicare Hospice Benefit], but hospices may 'otherwise demonstrate…that the patient has a terminal prognosis.'").

32. The application of hospice LCDs to a particular individual's circumstances is a complex clinical analysis that requires the appropriate medical knowledge, skill, experience, and

expertise. Hospice LCDs—particularly the Palmetto GBA ("Palmetto") hospice LCDs that apply here—are flexible and lack the more defined thresholds and exhaustive lists of factors present in the LCDs for other Medicare items and services. In fact, the Palmetto LCDs explicitly acknowledge that the relevant diagnoses "may support a prognosis of 6 months or less under many clinical scenarios," intentionally giving Certifying Physicians clinical leeway to determine, using clinical judgment, whether the structural and functional impairments and activity limitations associated with a patient's primary hospice diagnosis, together with any secondary and/or comorbid conditions, are such that most individuals with the same or similar impairments would have a prognosis of six months or less. *See, e.g.*, Palmetto GBA's LCDs for Hospice Alzheimer's Disease & Related Disorders (L34567), Hospice - Neurological Conditions (L34547), and Hospice Cardiopulmonary Conditions (L34548).

33. Because LCDs do not establish substantive legal standards, ALJs are "not bound by LCDs," but must give "substantial deference to [LCDs] if they are applicable to a particular case." 42 C.F.R. § 405.1062(a). If LCDs were rigid, all-or-nothing checklists for eligibility (*i.e.*, if they were to be afforded *complete* deference, rather than just substantial deference), they would (a) need to go through the § 1395hh notice-and-comment process and (b) interfere with physicians' exercise of clinical judgment. CMS was clear in the promulgation of the final rule passing the "substantial deference" regulatory standard that the standard "does not alter the ALJ's role as an independent fact finder," and that the regulation should not "lead to adjudicators 'rubber stamping' the previous appeal decision." *See* 74 Fed. Reg. 65296, 65327 (Dec. 9, 2009). LCDs themselves do not conclusively establish what is "reasonable and necessary" but, rather, are intended to serve as a "useful framework" to aid in physician decision-making regarding eligibility and facilitate ALJs' analysis of the individual facts presented to determine whether services provided were

"reasonable and necessary." *See* 70 Fed. Reg. 11419, 11458 (March 8, 2005); 42 U.S.C. § 1395y(a)(1)(A).[1]

34. Based on CMS commentary, if an individual meets LCD guidelines, then the ALJ must, in substantial deference to the LCD, determine that the individual is eligible for hospice. *See* 82 Fed. Reg. 4974, 5026 (stating that claims may be "denied in error as a result of [a reviewer's] non-compliance with…authority that is owed substantial deference, such as LCDs."). However, if an individual does not meet LCD guidelines, it does not necessarily follow that the individual is ineligible for hospice. The "substantial deference" standard requires ALJs to utilize LCDs as a basis to *allow* for reimbursement when the guidelines are met but *does not* permit ALJs to deny reimbursement solely because an individual does not squarely fall within the LCD. If, after undertaking an analysis as an independent factfinder, the ALJ determines that an individual does not satisfy LCD guidelines, the ALJ must consider all other relevant factors bearing on prognosis, including those beyond the confines of the LCD, in order to render a decision.

35. In cases where CMS or its contractors determine that an item or service is not reasonable and necessary, Section 1879 of the Social Security Act (the "Act"), codified at 42 U.S.C. § 1395pp, provides that payment shall nevertheless be made for such items or services if the provider did not know, and could not reasonably have been expected to know, that such items or services would not be covered. This liability limitation provision specifically applies to cases where CMS or its contractors determine that a Medicare hospice beneficiary was not terminally ill. 42 U.S.C. § 1395pp(g)(2).

[1] "Reasonable and necessary" is the ultimate standard ALJs are bound by under the Social Security Act for Medicare reimbursement. For hospice specifically, the standard for reimbursement is "reasonable and necessary for the palliation or management of terminal illness." 42 U.S.C. § 1395y(a)(1)(C).

36. If CMS determines a provider has been overpaid, Section 1870 of the Act, codified at 42 U.S.C. § 1395gg, allows for waiver of recoupment of the overpayment where the provider is deemed to be "without fault" with respect to creating the overpayment. A provider is "without fault" as to the creation of an overpayment, and thus entitled to waiver of recoupment of the overpayment, where it had a reasonable basis for assuming that the payments received were correct.

37. The Medicare program is administered by the Secretary through CMS which, in turn, contracts with private entities to perform certain functions on its behalf. These functions include, but are not limited to, claims processing for reimbursement submitted by Medicare providers and audits of such claims to ensure that they meet the requirements set forth in the Medicare statute and its implementing regulations.

38. Medicare claims are processed by MACs. Other CMS divisions or contractors, such as the CMS Center for Program Integrity ("CPI"), Zone Program Integrity Contractors ("ZPICs"), and Uniform Program Integrity Contractors ("UPICs") (which succeeded and replaced the ZPICs), were and are authorized by CMS to audit claims for payment presented to Medicare by health care providers relating to services they provided to Medicare beneficiaries. These audits were and are performed on a post-payment basis to ensure that the claims complied with Medicare coverage and documentation requirements at the time they were submitted for reimbursement.

39. In addition, HHS's Office of Inspector General ("OIG") audits health care providers that participate in Medicare pursuant to its authority to "conduct and supervise audits and investigations relating to the programs and operations" of HHS, including compliance with Medicare requirements. 5 U.S.C. § 402(b)(1).

40. However, as the OIG itself has acknowledged in this very case, "OIG audit recommendations do not represent final determinations by Medicare. CMS, acting through a MAC or other contractor, will determine whether overpayments exist and will recoup any overpayments consistent with its policies and procedures." OIG, *Medicare Hospice Provider Compliance Audit: Ambercare Hospice, Inc.* 6 n.25 (May 2021). *See also* 42 U.S.C. § 1395kk-1(a)(4)(A) (describing determination of the payment amount as a function of MACs).

41. If a CMS division, the OIG, or a CMS contractor audits and denies a claim, the affected provider may avail itself of an administrative appeals process to contest the claim denial(s). This appeals process consists of five stages: (i) redetermination, (ii) reconsideration, (iii) a hearing before an ALJ, (iv) review by the Council, and (v) judicial review by a federal district court.

42. Requests for redetermination are processed by MACs. Requests for reconsideration are handled by separate contractors known as Qualified Independent Contractors ("QICs"). Hearing requests are adjudicated by ALJs in OMHA. Requests for review are processed by the Council, which is a component of the HHS Departmental Appeals Board.

LEGAL FRAMEWORK: STATISTICAL SAMPLING AND EXTRAPOLATION

43. The "purpose" of Medicare program integrity audits is "identifying underpayments and overpayments and recouping overpayments," according to Section 1893(h)(1) of the Act, codified at 42 U.S.C. § 1395ddd(h)(1). *See also* 42 C.F.R. § 455.504 (defining the Medicare recovery audit contractor program as a program "to identify underpayments and overpayments and recoup overpayments"). An underpayment is defined as including "[n]onpayment, where payment was due but was not made." 20 C.F.R. § 416.536.

44. CMS sets forth instructions on performing statistical sampling and extrapolation in the Medicare Program Integrity Manual ("MPIM"), CMS Pub. No. 100-08. The purpose of these instructions is "to ensure that a statistically valid sample is drawn and that statistically valid methods are used to project an overpayment where the results of the review indicate that overpayments have been made." MPIM § 8.4.1.1.

45. ALJs are bound by "[a]ll laws and regulations pertaining to the Medicare and Medicaid programs," according to 42 C.F.R. § 405.1063(a). ALJs are not bound by "CMS program guidance, such as program memoranda and manual instructions, but will give substantial deference to these policies if they are applicable to a particular case." 42 C.F.R. § 405.1062(a).

46. However, the MPIM's statistical sampling and extrapolation guidelines are entitled only to *Skidmore* deference. *Rio Home Care, LLC v. Azar*, No. 7:17-CV-116, 2019 WL 1411805, at *26 (S.D. Tex. Mar. 11, 2019). In addition, because the MPIM has not been promulgated as a regulation by HHS, it cannot "establish[] or change[] a substantive legal standard governing the scope of benefits, the payment for services, or the eligibility of individuals, entities, or organizations to furnish or receive services or benefits" through the Medicare program. 42 U.S.C. § 1395hh(a)(2).

47. Further, the MPIM itself intends auditors to base their statistical sampling and extrapolation methodology on generally accepted statistical principles as well as the MPIM. *See* MPIM § 8.4.1.5 ("The sampling methodology used to project overpayments must be reviewed by a statistician, or by a person with equivalent expertise in probability sampling and estimation methods.…See section [8.4.10] for a list, not exhaustive, of texts that represent the minimum level of understanding that the statistical expert should have."); MPIM § 8.4.10 (listing several general statistical texts).

48. The auditor begins the sampling process by drawing from the data set the universe of claims, which "will consist of all fully and partially paid claims submitted by the provider for the period under review." MPIM § 8.4.3.2.1. Usually, the universe will "cover all relevant claims or line items for the period under review." MPIM § 8.4.3.2.

49. From the universe, the auditor will next select the sampling frame—a list of "all the possible sampling units from which the sample is selected." MPIM § 8.4.3.2.3. As the MPIM notes, "The ideal frame is a list that covers the target universe completely." *Id.*

50. The auditor then uses a sampling process to choose the sample from the sampling frame. *See* MPIM § 8.4.4.1 (noting that the most common sampling designs are simple random sampling, systematic sampling, stratified sampling, cluster sampling, or a combination).

51. After the sample is chosen, each claim in the sample is reviewed to determine whether the claim was paid appropriately, underpaid, or overpaid. *See* MPIM § 8.4.6.3 ("Document the amount of all overpayments and underpayments and how they were determined."). These results are used to calculate an error rate.

52. If extrapolation is used, the error rate is extrapolated across the entire universe to estimate total overpayment amount. *See* MPIM § 8.2.1.1 ("A projected overpayment is the numeric overpayment obtained by projecting an overpayment from statistical sampling for overpayment estimation to all similar claims in the universe under review.").

53. However, Section 1893(f)(3) of the Act, codified at 42 U.S.C. § 1395ddd(f)(3), prohibits Medicare auditors from using extrapolation unless HHS has determined there is a "sustained or high level of payment error" or failure of educational efforts to correct such errors. Accordingly, MPIM § 8.4.1.2 emphasizes that Section 1893(f)(3) "mandates that *before* using extrapolation to determine overpayment amounts…, there must be a determination of sustained or

high level of payment error, or documentation that educational intervention has failed to correct the payment error" (emphasis added).

54. At the time the audit began, MPIM § 8.4.1.4 stated that means of determining a sustained or high level of payment error included:

a. "error rate determinations by MR unit, PSC, ZPIC or other area"

b. "probe samples"

c. "data analysis"

d. "provider/supplier history"

e. "information from law enforcement investigations"

f. "allegations of wrongdoing by current or former employees of a provider or supplier"

g. "audits or evaluations conducted by the OIG"

55. Effective January 2, 2019, while the audit was still ongoing and before the initial results were issued, the "error rate determinations" criterion in MPIM § 8.4.1.4 was revised to read, "high error rate determinations by the contractor or by other medical reviews (i.e., greater than or equal to *50 percent* from a *previous* pre- or post-payment review)" (emphases added).

56. Under Section 1893(f)(3) of the Act and MPIM § 8.4.1.2, the determination of a high level of payment error is not subject to review. However, Section 1893(f)(3)'s prohibition against review violates providers' due process rights. In another recent case, another provider challenged the use of extrapolation by arguing that the Defendant's use of extrapolation without giving providers a meaningful process to challenge it violates providers' due process rights. *See* Complaint at 11–16, *Merit Leasing Co. v. Becerra*, No. 1:23-CV-859 (N.D. Ohio Apr. 24, 2023). The Defendant settled with the provider by agreeing to pay 88% of the amount owing to the

extrapolation. *See id.* at 3–4 (stating that after appeals, the alleged overpayment for claims in the sample was $37,304.69 and the total overpayment demand following extrapolation was $417,275.00); Stipulation of Settlement at 2, *Merit Leasing Co. v. Becerra*, No. 1:23-CV-859 (N.D. Ohio Mar. 7, 2024) (stating that the Defendant agreed to settle by paying $335,000.00).

57. Even if Section 1893(f)(3) did not violate providers' due process rights, neither Section 1893(f)(3) nor MPIM § 8.4.1.2 indicates that the question of *whether the auditor ever made such a determination* before deciding to extrapolate is likewise unreviewable.

58. Further, under both generally accepted statistical principles and the MPIM, statistical samplings are invalid if they do not result in a probability sample. *See* MPIM § 8.4.2. A probability sample is one in which each sample, and each unit of each possible sample, has "a known probability of selection." *Id.*

59. Relatedly, auditors must "document all steps taken in the random selection process exactly as done to ensure that the necessary information is available for anyone attempting to replicate the sample selection," MPIM § 8.4.4.2, and "maintain complete documentation of the sampling methodology that was followed," MPIM § 8.4.4.4. This includes documenting the universe definition and elements, period covered, sampling unit definitions and identifiers, dates of service, source, sampling frame, and the random numbers used and how they were selected. MPIM § 8.4.4.4.1. This same section requires that "[s]ufficient documentation…be kept so that the sampling frame can be re-created, should the methodology be challenged." *Id.*

60. The Medicare Appeals Council has reversed extrapolations because the auditor failed to maintain documentation necessary to replicate the sampling process, emphasizing its importance to providers' due process rights. *See*, e.g., *Glob. Home Care, Inc.*, M-11-116, at 4 (Medicare Appeals Council Jan. 11, 2011) ("The sampling frame cannot be recreated from the

documentation present. Without this basic documentation, a provider does not have the information and data necessary to mount a due process challenge to the statistical validity of the sample, as is its right under CMS Ruling 86-1."); *Podiatric Med. Assocs.*, M-10-230, at 20 (Medicare Appeals Council June 22, 2010) ("It is well-established that due process affords an appellant provider the right to examine audit results in order to mount a proper challenge in the appeals process….Absent supporting evidence, the appellant is deprived of its ability to review the extrapolation in question.").

61. When creating the sampling frame, auditors must include potential underpayments. In accordance with the statutory requirement to identify both underpayments and overpayments, as set forth in Section 1893(h)(1) of the Act, many sections of the MPIM require auditors to net underpayments against overpayments when estimating the total overpayment amount. *See*, *e.g.*, MPIM § 8.4.5.2 ("Sampling units that are found to be underpayments, in whole or in part, are recorded as negative overpayments and shall also be used in calculating the estimated overpayment."); MPIM § 8.4.5.1 ("In simple random or systematic sampling the total overpayment in the frame may be estimated by calculating the mean overpayment, net of underpayment, in the sample and multiplying it by the number of units in the frame."). For Corporate Integrity Agreements, the OIG itself has recently begun to explicitly require the inclusion of underpayments to calculate the overpayment demand. *See* OIG, HHS, Corporate Integrity Agreement Between the Office of Inspector General of the Department of Health and Human Services and CHC-FLA, LLC, App'x B, at 1 (Sept. 26, 2022), https://www.oig.hhs.gov/fraud/cia/agreements/CHC-FLA_Inc_09262022.pdf.

62. Auditors must also take care in determining the sample size, which has "a direct bearing on the precision of the estimated overpayment." MPIM § 8.4.4.3. Accordingly, the MPIM

instructs auditors not to choose a sample size arbitrarily but to consider multiple factors to determine the sample size. *See id.* ("It is neither possible nor desirable to specify a minimum sample size that applies to all situations. A determination of sample size may take into account many things, including the method of sample selection, the estimator of overpayment, and prior knowledge (based on experience) of the variability of the possible overpayments that may be contained in the total population of sampling units.")

63. Although the MPIM does not set a threshold for an acceptable precision, at the time this audit began, OIG itself required a precision higher than 25% for its Medicare claim reviews conducted against providers with whom it has Corporate Integrity Agreements, unless OIG used RAT-STATS or equivalent statistical software to choose the sample size. In addition, another federal district court case invalidated a contractor sampling and extrapolation because the precision of 32.5% was unacceptably high (a higher percentage reflecting a worse precision). *See Central Louisiana Home Health Care, L.L.C. v. Price*, No. 1:17-CV-00346, 2018 WL 7888523, at *20 (W.D. La. Dec. 28, 2018).

STATEMENT OF FACTS

64. The Hospice is one of the longest-standing providers of hospice care in New Mexico and has continuously served Medicare hospice beneficiaries in the state since its founding in 1994. Currently, the Hospice provides hospice services to New Mexicans across 29 counties.

65. In a letter dated February 22, 2018, the OIG, on behalf of CMS, informed the Hospice of its intention to audit sampled claims related to services provided by the Hospice between October 1, 2015 and September 30, 2017.

66. During an on-site visit that occurred the week of March 27, 2018, the OIG requested medical and billing records from the Hospice pertaining to a "random sample" of 100 claims

(totaling $397,050) out of 13,382 claims (totaling $53,845,604) the Hospice submitted for payment for services provided from January 1, 2016 through December 31, 2017. The Hospice promptly complied with this request and provided the OIG with thousands of pages of responsive records for review.

67. In a draft report dated September 17, 2020 ("Draft Report"), the OIG informed the Hospice that for 52 of the 100 claims reviewed, the clinical record did not support that the patients were terminally ill. Based on an extrapolation of the sample results, the OIG estimated that the Hospice received at least $24.6 million in unallowable Medicare reimbursement for hospice services. The Draft Report further recommended that the Hospice refund to Medicare the portion of the estimated $24,665,520.00 attributable to the claims that did not comply with Medicare requirements and fell within the four-year reopening period.

68. The Hospice responded to the Draft Report in a letter dated November 23, 2020. The response refuted the findings and recommendations set forth in the OIG's Draft Report by, among other things, providing rebuttal statements supporting clinical eligibility for 48 out of the 52 allegedly non-compliant claims. The response also included a report (dated November 23, 2020) prepared by statistical expert R. Mitchell Cox, Ph.D., identifying numerous flaws in the OIG's sampling and extrapolation methodology.

69. In its final report dated May 14, 2021 ("Final Report"), the OIG maintained the validity of its findings, recommendations, and sampling and extrapolation methodology. The Hospice then received a demand letter from its MAC, Palmetto GBA, LLC ("Palmetto"), dated June 2, 2021 asserting that the Hospice must refund to Medicare an overpayment amount of $6,471,637.00.

70. The Hospice initiated an appeal of the OIG's Final Report and Palmetto's demand letter through the Medicare administrative appeals process. On September 29, 2021, the Hospice filed a request for redetermination with Palmetto, seeking review of 17 of the 18 denied claims within the four-year reopening period. The redetermination request included a statistical expert report (dated September 23, 2021) revised by Dr. Cox in response to Palmetto's demand letter.

71. In a supplement to its redetermination request dated November 9, 2021, the Hospice submitted rebuttal statements prepared by board certified hospice physicians Christopher Allen Jones, MD, MBA, HMDC, FAAHPM, and Ruth M. Thomson, DO, MBA, HMDC, FACOI, FAAHPM, further supporting the medical necessity of the appealed claims.

72. In its redetermination decision dated November 23, 2021, Palmetto upheld, in whole or in part, the denial of all 17 claims at issue.

73. On May 24, 2022, the Hospice filed a request for reconsideration with C2C Innovative Solutions, Inc. ("C2C"), the QIC, appealing the denied claims. The reconsideration request included extensive physician clinical summaries prepared by expert physician Stephen A. Leedy, MA, HMDC, FAAHPM, and either Dr. Jones or Dr. Thomson, as well as a statistical expert report (dated March 21, 2022) revised by Dr. Cox in response to Palmetto's redetermination decision.

74. In its reconsideration decision dated July 22, 2022, C2C upheld the denial of all 17 claims pertaining to 17 patients.

75. On December 7, 2022, the Hospice filed a request for hearing before an ALJ, seeking review of all remaining denied claims. On January 2, 2023, the Hospice received notice that the appeal would be adjudicated by ALJ Steve Goga.

76. In advance of the scheduled ALJ hearing, on April 28, 2023, the Hospice submitted a position statement to ALJ Goga. The Hospice also provided copies of the position statement to Palmetto and C2C. The position statement summarized certain relevant legal, medical, and statistical authorities that supported the propriety of the claims at issue and demonstrated the invalidity of the OIG's sampling methodology and extrapolation.

77. The position statement also introduced and attached the curricula vitae of the Hospice's expert witnesses, including clinical expert Dr. Leedy and statistical expert Dr. Cox. In addition, the position statement included the written testimony of certifying physicians Levi Maes, Camila Jaramillo (formerly Tapia), and Karin Thron reaffirming their prior eligibility determinations reflected in the CTIs covering the claims at issue. Also included was a statistical expert report (dated April 24, 2023) revised by Dr. Cox in response to C2C's reconsideration decision.

78. In preparation for the ALJ hearing, Dr. Leedy applied his specialized skills and knowledge as a board-certified hospice physician and certified hospice medical director to analyze the medical records the Hospice previously submitted to the OIG, Palmetto, and C2C. Based on his analysis, Dr. Leedy arrived at an expert opinion concerning whether the medical records supported the conclusions of the certifying physicians that each patient at issue had a "terminal illness" during the dates of service under review.

79. The hearing took place before ALJ Goga on May 8 and 11, 2023. No party other than the Hospice appeared at the hearing.

80. At the hearing, Dr. Leedy provided medical opinion testimony on behalf of the Hospice and was the *only* expert physician witness to testify. Dr. Cox, the only expert statistician to testify, explained how, based on his thorough analysis of the statistical sampling and

extrapolation materials received from the OIG and Palmetto, the sampling and extrapolation were statistically invalid.

81. Despite the unrefuted expert medical opinion testimony supporting the propriety of the claims at issue and expert statistical testimony indicating that the sampling and extrapolation were invalid, ALJ Goga issued a decision on June 28, 2023 (the "Decision") that upheld the denial of all 17 appealed claims and found that the statistical sampling and extrapolation methodology were valid.

82. On August 25, 2023, the Hospice submitted to the Council a Request for Review of Administrative Law Judge Medicare Decision seeking review of ALJ Goga's Decision. In an exhibit to its submission to the Council, the Hospice provided additional details and examples demonstrating the errors ALJ Goga made in the Decision. That exhibit is attached hereto as Exhibit A and incorporated herein by reference.

83. The Council did not issue a final decision or dismissal order or remand the case to the ALJ within 90 calendar days of receipt of the Hospice's Request for Review. *See* 42 C.F.R. § 405.1100(c). Accordingly, on January 11, 2024, the Hospice properly requested that the appeal be escalated to federal district court as permitted by 42 C.F.R. § 405.1132(a). On January 23, 2024, the Council issued an order granting the Hospice's request for escalation.

84. The Hospice has thus exhausted its administrative remedies, and this case is eligible for judicial review.

85. This Complaint is timely filed within 60 calendar days after the Hospice received the Council's order. *See* 42 C.F.R. § 405.1132(b).

COUNT I: VIOLATION OF THE MEDICARE ACT AND ADMINISTRATIVE PROCEDURE ACT

The ALJ Applied the Incorrect Legal Standards.

86. The Hospice hereby incorporates by reference paragraphs 1 through 85 herein.

87. The failure to apply the correct legal standards or to provide the Court with a sufficient basis to determine that appropriate legal principles have been followed is grounds for reversal.

88. The ALJ applied incorrect legal standards when she committed errors including, but not limited to, those described in Exhibit A.

89. Based on this failure to apply the correct legal standards, the Decision should be reversed.

The ALJ's Decision is not Supported by Substantial Evidence.

90. The Hospice hereby incorporates by reference paragraphs 1 through 89 herein.

91. The ALJ's Decision must be supported by "substantial evidence," and where reliance is placed on one portion of the record in disregard of over-balancing evidence to the contrary, the Court may reverse the Decision.

92. The unfavorable determinations in the ALJ's Decision were not supported by substantial evidence and were contrary to the overwhelming weight of the evidence, as explained in Exhibit A.

93. The medical records and the unrefuted expert witness testimony provided by Dr. Leedy show, by a preponderance of the evidence, that the patients had terminal prognoses of six months or less if their illnesses ran the normal course.

94. Without a rational basis, the ALJ disregarded the uncontested opinions of the only physician expert to testify at the hearing and improperly made medical conclusions she is

unqualified and unauthorized to make regarding the patients' prognoses without the support of any admissible medical opinion evidence.

95. The ALJ failed to give appropriate weight and deference to the certifying physicians' clinical judgment, despite acknowledgment by Congress and CMS that a hospice physician's role is central to the Medicare Hospice Benefit.

96. The ALJ's approval of the statistical sampling and extrapolation was also unsupported by substantial evidence. Through Dr. Cox's expert reports and uncontested testimony, the Hospice provided overwhelming evidence of many fatal problems with the sampling and extrapolation.

97. Despite the strength of this evidence, the ALJ upheld the sampling and extrapolation without providing any substantive analysis. Aside from copying and pasting large block quotes from the MPIM and restating how the MAC and QIC decided, ALJ Goga wrote only five sentences addressing his findings regarding the statistical sampling and extrapolation. He wrote merely that the Hospice had "not provided sufficient argument" to show that the methodology was inappropriate or that errors were made during the calculations. He also wrote that Dr. Cox had "not pointed to any violation of the Medicare Program Integrity Manual." However, even this statement is patently incorrect, as Dr. Cox identified many specific MPIM violations in his expert reports and in his testimony.

98. The dearth of substance to support the ALJ's Decision shows that the Decision was unsupported by substantial evidence. Rather, the ALJ's approval of the sampling and extrapolation was a mere rubber stamp.

99. As a result of the absence of substantial evidence supporting the Decision, the Decision should be reversed.

The ALJ Failed to Give Reasons for Upholding the Statistical Sampling and Extrapolation.

100. The Hospice hereby incorporates by reference paragraphs 1 through 99 herein.

101. The ALJ's Decision must include "findings and conclusions, and the reasons or basis therefor, on all the material issues of fact, law, or discretion presented on the record."

102. However, the ALJ's Decision failed to give reasons for finding that the statistical sampling and extrapolation were invalid.

103. Because the ALJ failed to give reasons for finding that the statistical sampling and extrapolation were valid, the Decision should be reversed.

COUNT II: VIOLATION OF THE MEDICARE PROGRAM INTEGRITY MANUAL

104. The Hospice hereby incorporates by reference paragraphs 1 through 103 herein.

105. The MPIM intends auditors to base their statistical sampling and extrapolation methodology on generally accepted statistical principles as well as the MPIM.

106. The Defendant violated generally accepted statistical principles and the MPIM in multiple ways, including without limitation:

a. Neither the OIG nor CMS has ever indicated that either agency made a determination of a sustained or high level of payment error before the audit began. Rather, the Defendant decided to extrapolate *before* making a determination of a sustained or high level of payment error, violating MPIM § 8.4.1.2 (as well as Section 1893(f)(3) of the Act). In addition, the Defendant may not extrapolate in the same review that supposedly determines a high level of error. As the 2019 clarification to MPIM § 8.4.1.4 states, extrapolation cannot be used until there has been a "*previous*… review" showing a high error rate (emphasis added);

b. The statistical sampling was invalid because it did not result in a probability sample. The OIG failed to produce any evidence showing that it decided how to order the claims within the sampling frame or chose the random number seed *before* beginning the sampling process. As a result, neither each sample nor each unit of each sample had "a known probability of selection" when sampling began, as required by generally accepted statistical principles and MPIM § 8.4.2. Because it did not result in a probability sample, the sampling was invalid;

c. By failing to produce evidence that all the parameters needed to produce the sample were chosen before sampling began, auditors can run multiple samples and choose the one likely to generate the highest overpayment estimate. In such circumstances, providers would be highly unlikely to be able to detect and prove such activity;

d. According to the OIG's sampling plan, the OIG removed all claims paid less than $1,000, including claims paid zero dollars, from the sampling frame. Statistically, exclusion of claims paid less than $1,000 served only to artificially inflate the overpayment estimate. This also violated the many sections of the MPIM that require auditors to net underpayments against overpayments when estimating the total overpayment amount (as well as the statutory command to identify underpayments as well as overpayments); and

e. Instead of using statistical software or considering multiple factors to determine an appropriate sample size, the OIG arbitrarily chose a sample size of 100—the same sample size that the OIG has used in at least seven other audits reviewed by Dr. Cox. Choosing a sample size without undertaking any analysis to determine whether the sample size is adequate violates generally accepted statistical

principles. It also violates MPIM § 8.4.4.3's specific directive not to "specify a minimum sample size that applies to all situations."

f. The OIG's selection of an inadequate sample size resulted in an unacceptably high (poor) precision of 36.28%. This means that, in the event the Hospice is asked to reimburse more than it has been overpaid, it will be asked to over-reimburse more than three and a half times the amount it would have been asked to reimburse had the precision been a more standard 10%.

107. Because of the Defendant's multiple, serious violations of generally accepted statistical principles and the MPIM, the Decision should be reversed.

COUNT III: VIOLATION OF THE SOCIAL SECURITY ACT

The ALJ Failed to Limit the Hospice's Liability as Required by Section 1879(a) and (g)(2).

108. The Hospice hereby incorporates by reference paragraphs 1 through 108 herein.

109. Section 1879(a) and (g)(2) of the Act limit the Hospice's liability for any alleged overpayments.

110. Section 1879 provides financial relief to beneficiaries, providers, practitioners, and other suppliers who acted in good faith in accepting or providing services found to be not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member. *See* Medicare Financial Management Manual, CMS Pub. 100-06, Ch. 3 § 70.1.

111. The protection afforded under Section 1879 was expanded in 1997 specifically to guard hospice beneficiaries and providers from liability arising from "incorrect" diagnoses of terminal illness in cases where the beneficiary and/or provider "did not know and could not

reasonably have been expected to know" that the diagnoses were incorrect. *See* 42 U.S.C. §§ 1395pp(a) and (g)(2); *see also* Cong. Rec. E1084 (June 3, 1997).

112. The ALJ's Decision fails to properly interpret and apply the limitation of liability provision of Section 1879(a) and (g)(2) in that the ALJ concluded that the Hospice knew or should have known that the services it provided to the patients at issue would not be covered by Medicare (*i.e.*, that the patients were not terminally ill) simply because, the Hospice "is a provider, and is presumed to have knowledge of Medicare rules and procedures."

113. Therefore, the ALJ's Decision should be reversed, and this Court should rule that the Hospice is entitled to the limitation of liability for the full value of the denied claims.

The ALJ Failed to Waive the Alleged Overpayment as Required by Section 1870.

114. The Hospice hereby incorporates by reference paragraphs 1 through 113 herein.

115. Section 1870 of the Act waives the Hospice's liability for the alleged overpayment.

116. Under Section 1870, a provider is "without fault" if it "exercised reasonable care in billing for, and accepting, the payment" (*i.e.*, it had a reasonable basis for assuming that the payment was correct). *See* Medicare Financial Management Manual, CMS Pub. 100-06, Ch. 3 § 90.

117. The ALJ's Decision does not explain how the Hospice was unreasonable in assuming that the services were reasonable and necessary and the payments correct. Specifically, the ALJ neglected to explain how access to or knowledge of "widely published CMS manuals and readily available regulations" equates to knowledge that the specific patients at issue were not terminally ill—a determination that requires the clinical judgment of a physician, rather than the application of any CMS rule or guidance.

118. As a matter of law and fact, the Hospice is "without fault," and its liability must be waived as to all denied claims.

The Use of Extrapolation Violated Section 1893(f)(3).

119. The Hospice hereby incorporates by reference paragraphs 1 through 118 herein.

120. The Defendant's use of extrapolation violated Section 1893(f)(3) of the Act. The Defendant did not make a determination that there was a "sustained or high level of payment error" before deciding to extrapolate. In fact, the OIG tacitly admitted as much. In its final report, the OIG stated, "The statutory and manual requirement that a determination of a sustained or high level of payment errors must be made before extrapolation can be used applies only to Medicare contractors." OIG, *Medicare Hospice Provider Compliance Audit: Ambercare Hospice, Inc.* 6 n.25 (May 2021).

121. Although the MPIM states that "audits or evaluations conducted by the OIG" are one possible criterion that may be used to determine a sustained or high level of payment error," this blatantly conflicts with the statute. The simple fact that the OIG is performing a review cannot establish that a payment error is high.

122. The payment error rate in this audit is well below the 50% threshold that Defendant set before the results of this audit were issued.

123. Because the use of extrapolation violated Section 1893(f)(3) of the Act, this Court should declare that the extrapolation was statutorily unauthorized and should enjoin the Defendant from using extrapolation in this case.

COUNT IV: VIOLATION OF THE HOSPICE'S DUE PROCESS RIGHTS UNDER THE U.S. CONSTITUTION

The Prohibition Against Review Violates the Hospice's Due Process Rights.

124. The Hospice hereby incorporates by reference paragraphs 1 through 123 herein.

125. The Hospice has a protected property interest because it is entitled to payments for services that met the federal hospice Conditions of Payment.

126. Both CMS (through Ruling 86-1) and the Medicare Appeals Council have acknowledged that statistical sampling and extrapolation implicate providers' due process rights.

127. The prohibition against administrative and judicial review of HHS's determination that there has been a sustained or high level of payment error, as set forth in Section 1893(f)(3) of the Act and MPIM § 8.4.1.2, deprives the Hospice of an appropriate level of process. Extrapolation vastly multiplies overpayment estimates—as well as any unresolved errors the auditor has made. Thus, the Hospice faces a tremendous risk that it will be erroneously deprived of funds to which it was entitled if the sole determination that authorizes the extrapolation is unreviewable.

128. Therefore, this statutory and agency prohibition against review violates the Hospice's due process rights under the U.S. Constitution.

129. Because the prohibition against review violates providers' due process rights, this Court should declare that the prohibition against review of the Defendant's determination of a high level of payment error, which are set forth in Section 1893(f)(3) and MPIM § 8.4.1.2, violates the due process clauses of the Fifth and Fourteenth Amendments of the U.S. Constitution. Moreover, this Court should enjoin the Defendant from using extrapolation in this case.

The Decision to Use Extrapolation Violated the Hospice's Due Process Rights.

130. The Hospice hereby incorporates by reference paragraphs 1 through 129 herein.

131. The Defendant's decision to use extrapolation violated the Hospice's due process rights because the Defendant decided to use extrapolation *before* making a determination of a sustained or high level of payment error. This decision deprived the Hospice of an appropriate level of process because it permitted the Defendant to decide to extrapolate for any reason or for

no reason at all. Thus, the Hospice is highly likely to be erroneously deprived of funds to which it was entitled.

132. Because the Defendant decided to extrapolate before making a determination of a sustained or high level of payment error, this Court should declare that the Defendant violated the Hospice's due process rights and should enjoin the Defendant from using extrapolation in this case.

The Exclusion of Claims Paid Less than $1,000 Violated the Hospice's Due Process Rights.

133. The Hospice hereby incorporates by reference paragraphs 1 through 132 herein.

134. The Defendant's exclusion of all claims paid less than $1,000 violated the Hospice's due process rights. Excluding such claims serves no purpose other than to artificially inflate the overpayment estimate. Making things worse, the estimated overpayment total for the sample of claims that were reviewed was then extrapolated across the entire universe, including claims paid less than $1,000. The exclusion of these claims from the sampling frame placed the Hospice at tremendous risk of being erroneously deprived of funds to which it was entitled.

135. Because the Defendant wrongfully excluded claims paid less than $1,000 from the sampling frame, this Court should declare that the Defendant violated the Hospice's due process rights and reverse the ALJ's Decision that the sampling and extrapolation were valid.

The Multiple Fatal Statistical Errors Violated the Hospice's Due Process Rights.

136. The Hospice hereby incorporates by reference paragraphs 1 through 135 herein.

137. The Defendant's failure to adhere to generally accepted statistical principles and its own guidance, the MPIM, violated the Hospice's due process rights.

138. The Defendant decided to extrapolate before determining that there was a high level of payment error, ensured an artificially inflated overpayment by excluding claims paid less than

$1,000, chose the sample size arbitrarily and without undertaking any analysis, used a statistically invalid sample (i.e., not a probability sample), and then used the results to perform the unauthorized extrapolation the Defendant had planned to use from the beginning. Under any one of these circumstances, the Hospice's risk of being erroneously deprived of funds to which it was entitled was terribly high.

139. As a result of the Defendant's many fatal failures to adhere to generally accepted statistical principles and the MPIM, this Court should declare that the Defendant violated the Hospice's due process rights and reverse the ALJ's Decision that the sampling and extrapolation were valid.

The ALJ's Analysis of the Statistical Issues Violated the Hospice's Due Process Rights.

140. The Hospice hereby incorporates by reference paragraphs 1 through 139 herein.

141. The ALJ's perfunctory analysis of the Defendant's statistical methodology violated the Hospice's due process rights. He failed to give any reasons for finding that the statistical sampling and extrapolation were invalid—beyond the patently incorrect statement that the Hospice's statistician failed to identify any violations of the MPIM. The absence of any substantive analysis shows that the ALJ's approval of the statistical methodology was merely a rubber stamp. This falls far short of adequate process. As a result, the Hospice was at tremendous risk of being erroneously deprived of funds to which it was entitled.

142. Because the ALJ provided no substantive analysis of the statistical methodology, this Court should declare that the Defendant violated the Hospice's due process rights and reverse the ALJ's Decision that the sampling and extrapolation were valid.

REQUEST FOR RELIEF

WHEREFORE, the Hospice respectfully requests that this Court:

143. Find the ALJ's Decision applied the wrong legal standards;

144. Find the ALJ's Decision was not supported by substantial evidence;

145. Reverse the ALJ's Decision that the remaining denied claims did not meet Medicare coverage guidelines for hospice services;

146. Reverse the ALJ's Decision that the sampling and extrapolation were valid;

147. Declare that extrapolation was statutorily unauthorized in this case;

148. Enjoin the Defendant from using extrapolation in this case;

149. Reverse the ALJ's Decision that payment for the denied services cannot be made in accordance with Section 1879 of the Act;

150. Reverse the ALJ's Decision that recoupment of the alleged overpayment cannot be waived in accordance with Section 1870 of Act;

151. Declare that Section 1893(f)(3)'s prohibition against review of the Defendant's determination of a high level of payment error violates the due process clauses of the Fifth and Fourteenth Amendments of the U.S. Constitution.

152. Declare that the Defendant violated the Hospice's due process rights under the U.S. Constitution.

153. Hold that the Hospice is entitled to reimbursement for the claims submitted relating to Medicare that form the basis of this Complaint; and

[The remainder of this page is intentionally left blank.]

154. Grant the Hospice any other legal or equitable relief that the Court may deem just and proper.

Date: March 22, 2024.

Respectfully Submitted,

By: 

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